

**BEST AVAILABLE COPY**

Sheet 1 of 7  
MAR 11 2003  
L No. 17-227-1  
ENTERED

Form PTO-1449 (Rev. 8-88)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.  C-3407/1/US	Serial No.  10/047,557 1000/2900
O P F INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant  Gao et al.	
		Filing Date  January 15, 2002	Group No.  1614

TECH CENTER 211 2003  
MAR 10 2003  
PATENT & TRADEMARK OFFICE

## **U.S. PATENT DOCUMENTS**

Examiner Initial*		Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
MPY		5,360,615	Nov 01, 1994	Yu et al.	424	455	
		5,491,154	Feb 13, 1996	Ciceri et al.	514	356	
		5,676,968	Oct 14, 1997	Lipp et al.	424	448	
		6,071,916	Jun 06, 2000	Askin et al.	514	253	
		6,177,101	Jan 23, 2001	Martino et al.	424	464	
		2002/0006443	Jan 17, 2002	Curatolo et al.	424	486	
		6,379,707	Apr 30, 2002	Vladyka, Jr., et al.	424	502	

## **FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
MAY	EP 0 901 786	Mar 17, 1999	EP	A61K	9/14		
	EP 0 927 555	Jul 07, 1999	EP	A61K	31/12		
	EP 1 027 885	Aug 16, 2000	EP	A61K	9/14		
	EP 1 027 886	Aug 16, 2000	EP	A61K	9/14		
	WO 9744028	Nov 27, 1997	WO	A61K	31/365		
	WO 01/41536	Jun 14, 2001	WO				
	WO 01/78724	Oct 25, 2001	WO	A61K	31/41		
	WO 01/91750	Dec 06, 2002	WO	A61K	31/41		
	WO 02/05799	Jan 24, 2002	WO	A61K	31/415		
				.K	31/00		

**OTHER DOCUMENTS** (Including author, title, date, pertinence)

(*at pages, etc.*)

MRS	Asmussen & Heinz, Wirkstoffliberation in vitro bei Digoxin-Präparaten mit hoher Bioverfügbarkeit, <i>Arzneimittelforschung, Drug Res.</i> 30(12), pp. 2168-2172 (1980).
↓	Davis & Hadgraft, Effect of supersaturation on membrane transport: 1. Hydrocortisone acetate, <i>International Journal of Pharmaceutics</i> , 76, pp. 1-8, (1991).
↓	Doherty & York, The In-vitro pH-Dissolution Dependence and In-vivo Bioavailability of Frusemide-PVP Solid Dispersions, <i>J. Pharm. Pharmacol.</i> , 41, pp. 73-78, (1989).
Examiner <i>Marta Pauli-York</i>	Date Considered 11/23/03

O I P E  
MAR 10 2003

## BEST AVAILABLE COPY

Sheet 1 of 6

RECEIVED  
MAR 11 2003  
TECH CENTER 1600/2900Form PTO-1449  
(Rev. 8-88)U.S. Department of Commerce  
Patent and Trademark Office

Attorney Docket No.

C-3407/1/US

Serial No.

10/047,717

Applicant

Gao et al.

Filing Date

January 15, 2002

Group No.

1614

INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

## OTHER DOCUMENTS (Including author, title, date, pertinent pages, etc.)

MPL	Fujioka & Tan, Biopharmaceutical Studies on Hydantoin Derivatives. III. Physico-Chemical Properties, Dissolution Behavior, and Bioavailability of the Molecular Compound of 1-Benzene sulfonyl-5,5-Diphenylhydantoin and Antipyrene, <i>J. Pharm. Dyn.</i> , 5, pp. 475-484, (1982).
	Fujii et al., Dissolution and Bioavailability of Phenobarbital in Solid Dispersion with Phosphatidylcholine, <i>Chem. Pharm. Bull.</i> , Vol. 39., pp. 1886-1888, (1991).
	Higuchi, Physical Chemical Analysis of Percutaneous Absorption Process From Creams and Ointments, <i>Journal of the Society of Cosmetic Chemists</i> , 11, pp. 85-97, (1959).
	Higuchi & Farvar, Drug Membrane Transport Enhancement Using High Energy Drug-Povidone Coprecipitates, <i>Proc. Int. Symp.</i> , pp. 71-79, (1993).
	Iervolino et al., Penetration enhancement of ibuprofen from supersaturated solutions through human skin, <i>International Journal of Pharmaceutics</i> , 212, pp. 131-141, (2001).
	Kondo et al., Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug, <i>Journal of Pharmaceutical Sciences</i> , Vol. 83, No. 4, pp. 566-570, (1994).
	Kohri et al., Improving the Oral Bioavailability of Albendazole in Rabbits by the Solid Dispersion Technique, <i>J. Pharm. Pharmacol.</i> , 51, pp. 159-164, (1999).
	Ledwidge & Corrigan, Effects of surface active characteristics and solid state forms on the pH solubility profiles of drug-salt systems, <i>International Journal of Pharmaceutics</i> , 174, pp. 187-200, (1998).
	Loftsson & Sigurðardóttir, The effect of polyvinylpyrrolidone and hydroxypropyl methylcellulose on HPβCD complexation of hydrocortisone and its permeability through hairless mouse skin, <i>European Journal of Pharmaceutical Sciences</i> , 2, pp. 297-301, (1994).
	Loftsson et al., The effect of water-soluble polymers on aqueous solubility of drugs, <i>International Journal of Pharmaceutics</i> , 127, pp. 293-296, (1996).
	Megrab et al., Oestradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation, <i>Journal of Controlled Release</i> , 36, pp. 277-294, (1995).
	Moser et al., Stabilization of supersaturated solutions of a lipophilic drug for dermal delivery, <i>International Journal of Pharmaceutics</i> , 224, pp. 169-176, (2001).
	O'Driscoll & Corrigan, Chlorothiazide-Polyvinylpyrrolidone (PVP) Interactions: Influence on Membrane Permeation (Everted Rat Intestine) and Dissolution, <i>Drug Development and Industrial Pharmacy</i> , 8(4), pp. 547-564, (1982).
	Raghavan et al., Effect of cellulose polymers on supersaturation and in vitro membrane transport of hydrocortisone acetate, <i>International Journal of Pharmaceutics</i> , 193, pp. 231-237, (2000).
	Raghavan et al., Crystallization of hydrocortisone acetate: influence of polymers, <i>International Journal of Pharmaceutics</i> , 212, pp. 213-231, (2001).
	Raghavan et al., Membrane transport of hydrocortisone acetate from supersaturated solutions; the role of polymers, <i>International Journal of Pharmaceutics</i> , 221, pp. 95-105, (2001).
	Serajuddin & Jarowski, Influence of pH on Release of Phenytoin Sodium from Slow-Release Dosage Forms, <i>Journal of Pharmaceutical Sciences</i> , Vol. 82, No. 3, pp. 306-310, (1993).
MPL	Simonelli et al., Inhibition of Sulfathiazole Crystal Growth by Polyvinylpyrrolidone, <i>Journal of Pharmaceutical Sciences</i> , Vol. 59, No. 5, pp. 633-638, (1970).

Examiner

*Muth Pally*

Date Considered

9/23/03

\*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP §609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

RECEIVED  
Sheet 3 of 3

Form PTO-1449 (Rev. 8-88)		U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No. <b>C-3407/1/US</b>	Serial No. <b>MAR 10/047,222 1 2003</b>
		INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant <b>Gao et al.</b>	<b>TECH CENTER 1600/2000</b>
			Filing Date <b>January 15, 2002</b>	Group No. <b>1614</b>
<b>OTHER DOCUMENTS</b> (Including author, title, date, pertinent pages, etc.)				
<i>mfg</i>		Simonelli et al., Dissolution Rates of High Energy Sulfathiazole-Povidone Coprecipitates II: Characterization of Form of Drug Controlling Its Dissolution Rate via Solubility Studies, <i>Journal of Pharmaceutical Sciences</i> , Vol. 65, No. 3, pp. 355-361, (1976).		
<i>1</i>	<i>5</i>	Suzuki & Sunada, Comparison of Nicotinamide, Ethylurea and Polyethylene Glycol as Carriers for Nifedipine Solid Dispersion Systems, <i>Chem. Pharm. Bull.</i> , 45(10), pp. 1688-1693, (1997).		
		Suzuki & Sunada, Some Factors Influencing the Dissolution of Solid Dispersions with Nicotinamide and Hydroxypropylmethylcellulose as Combined Carriers, <i>Chem. Pharm. Bull.</i> , 46(6) pp. 1015-1020, (1998).		
		Yamada et al., Effect of Grinding with Hydroxypropyl Cellulose on the Dissolution and Particle Size of a Poorly Water-Soluble Drug, <i>Chem. Pharm. Bull.</i> , 47(9), pp. 1311-1313, (1999).		
<i>↓</i>		Yamamoto et al., Dissolution Behavior and Bioavailability of Phenytoin from a Ground Mixture with Microcrystalline Cellulose, <i>Journal of Pharmaceutical Sciences</i> , Vol. 65, No. 10, pp. 1484-1488, (1976).		
Examiner	<i>Mark Halligan</i>		Date Considered	<i>9/23/03</i>
<small>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP §609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small>				

**BEST AVAILABLE COPY**